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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,354	02/16/2000	David K. Swanson	1928-F	6203

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EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/505,354	SWANSON ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/26/00; 11/29/00; 4/6/01; 4/23/01; 6/21/01; 7/18/01; 4/18/02; 10/7/02; 1/8/03; 2/24/03; 1/23/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Preliminary Amendment

Applicant's preliminary amendment of July 11, 2000 canceled all previously pending claims and added new claims numbered 45-62. However, the highest numbered claim previously pending in the application was claim 43. As such, the newly added claims have been renumbered as claims 44-61 with appropriate changes to the dependencies of the claims. Applicant should also make not of the renumbering and reflect the renumbering of the claims in subsequent responses. All references to the application claims in the instant Office action are made with respect to the claims as renumbered.

Claims 50-61 of this application have been copied by the applicant from U. S. Patent No. 6,012,457. These claim are not patentable to the applicant because of the rejections set forth in the following Office action.

An interference cannot be initiated since a prerequisite for interference under 37 CFR 1.606 is that the claim be patentable to the applicant subject to a judgement in the interference.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51, 56 and 58-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 51 recites ablating a circumferential region between an arrhythmogenic origin located along the pulmonary vein and the left atrium. There is no specific disclosure of performing such a step in the instant application. While the instant application does support the creation of a circumferential lesion, there is no specific disclosure of specifically performing the method step of isolating an arrhythmogenic origin located along the pulmonary vein. Applicant contends that creation of the circumferential lesion would inherently isolate an origin located along the pulmonary vein (page 32 of applicant's July 11, 2000 communication) when the origin happens to be located there. While it certainly would be true, such happenstance does not explicitly provide support for the method step as recited. The method steps of claim 51 clearly acknowledges that the location of the arrhythmia origin is located in the pulmonary vein and seeks to isolate that origin. The instant application specification, on the other hand, makes no specific mention of locating an arrhythmia origin in the pulmonary vein then taking steps to isolate that origin. Since applicant has not identified a specific method of identifying and isolating an arrhythmia located in the pulmonary vein, applicant can not assert support for performing such a step on the premise that it would inherently perform the step on the occasion that such an arrhythmia origin were located in a pulmonary vein.

Claim 56 recites the step of ablating an elongate region of tissue along the left atrial wall with a linear lesion ablation element. Claim 56 depends from claim 50 which

recites the method step of creating a circumferential lesion around a pulmonary vein using an expandable member. The examiner agrees that applicant's specification supports the creation of a circumferential lesion in accordance with claim 50. Also, the examiner notes that applicant's specification makes mention of numerous embodiments, some of which are used to create linear lesions in the left atrial wall. However, there is nothing in the instant application specification which indicates a linear lesion is created in a left atrial wall in a procedure that creates a circumferential lesion around a pulmonary vein as set forth in the instant application claims. If anything, it appears as though the instant specification supports creation of either a circumferential lesion using the device as depicted in Figure 13, or provides an alternative device for creating linear lesions (Figures 27 and 28) in atrial tissue. There is no disclosure that the two embodiments are used in the same method.

Claims 58-61 recite various alternative forms of energy used to create the circumferential lesion. Claim 58 recites the use of cryogenic energy, claim 59 recites the use of an ablative fluid, claim 60 recites the use of microwave energy and claim 61 recites the use of optical ablation energy. The examiner maintains that there is insufficient support in the specification to enable one of ordinary skill in the art to use such alternative ablation modalities with the embodiment in applicant's Figure 13. It is noted that a general statement is made in applicant's specification that these alternative energy sources may be used with the ablation element (specification page 18, lines 8-24). However, there is no discussion of how such energy forms may be employed with

the embodiment of Figure 13. Each of the alternative energy sources would require a very specific delivery mechanism for delivering the energy to tissue.

For instance, the delivery of a cryogen and/or a chemical substance would require a passage through the ablation member (42(6)), and there is no disclosure of such a passage. Moreover, the delivery of a cryogen to tissue requires the use of very specific materials that can handle the extreme temperatures associated with cryogenic fluids. Applicant's specification disclose the "hoop" embodiment of Figure 13 as having a hoop formed from a resilient inert material like Nitinol, metal or silicone rubber (specification page 46, lines 33-35). There is no indication that these materials could be provided in the resilient form necessary to spring open and have the necessary qualities for delivering a cryogenic or ablative chemical. With further regard to the use of a cryogen, applicant's specification never recites the use of a cryogen. Page 18, lines 20-24 suggests that tissue could be performed by cooling. However, this is not an explicit disclosure of the use of a cryogen. While cryogen is one typical means by which tissue is cooled for ablation, there are other means to cool tissue for ablation, such as the use of thermoelectric cooling electrodes.

Similarly, the use of microwave energy and laser energy presents other delivery issues which are not enabled and/or supported by applicant's specification. A microwave energy emitter would typically require a coaxial antenna and would radiate energy in all directions (unless provided with a blocking mechanism to radiate in a particular direction). A laser energy source would require a delivery means such as an optical fiber. There is nothing in applicant's specification that would enable one of

ordinary skill in the art to make the resilient member of Figure 13 with the necessary structural components to delivery microwave and/or laser energy.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 115-147 of copending Application No. 09/870,288. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of application claims recite the same general procedure for creating circumferential lesions with only minor, obvious variations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

mp
September 16, 2005